

Larry Hogan | Governor

Boyd Rutherford | Lt. Governor

R. Michael Gill | Secretary of Commerce

Benjamin H. Wu | Deputy Secretary of Commerce

December 18, 2018

The Honorable Thomas V. Mike Miller, Jr. President, Maryland Senate State House, H-107 Annapolis, Maryland 21401-1991

The Honorable Michael E. Busch Speaker, Maryland House of Delegates State House, H-101 Annapolis, Maryland 21401-1991

RE: Maryland Life Sciences Advisory Board Report

Dear President Miller and Speaker Busch:

In accordance with Economic Development Article §3-205 the Maryland Life Sciences Advisory Board, in conjunction with the Department of Commerce is pleased to submit the annual Maryland Life Sciences Advisory Board Report.

We look forward to your review of this report and will be happy to furnish any additional information that is needed. If we can be of further assistance, or if you have any questions regarding this report, please contact Bret Schreiber, Executive Staff to the Maryland Life Science Advisory Board at 410-767-2368.

Sincerely,

Jay X. Verman, MD

Chairman, LSAB

R. Michael Gill

Secretary, Department of Commerce

Enclosure



2018 ANNUAL REPORT OF THE

MARYLAND LIFE SCIENCES ADVISORY BOARD

As Required by Economic Development Article

Section 3-205

Respectfully submitted to the General Assembly of Maryland by

R. Michael Gill

Maryland Department of Commerce

401 East Pratt Street

Baltimore, MD 21202

December 2018



Larry Hogan, Governor | Boyd Rutherford, Lt. Governor

Introduction

The Life Sciences Advisory Board (LSAB) was established by Chapter 304, Acts of 2007, for the purpose of maintaining Maryland's preeminence in the life sciences industry. The function of the board is to:

- Develop a comprehensive strategic plan for life sciences in the State of Maryland;
- Promote life sciences research, development, commercialization and manufacturing in Maryland;
- Promote collaboration and coordination among life science organizations in Maryland;
- Promote collaboration and coordination among research institutions of higher education in Maryland;
- Develop a strategy to coordinate state and federal resources to attract private sector investment and job creation in the life sciences;
- Develop a strategy to support federal life sciences facilities located in the state, including support for education, transportation, housing and capital investment needs; and
- Make recommendations to address critical needs in the life sciences, including access to venture capital and capital construction funding.

In performing its duties, the LSAB is to give due consideration to the business, scientific, medical, and ethical aspects of the life sciences industry.

Fiscal Year 2018 Board Composition

The current LSAB was appointed by Governor Larry Hogan on February 13, 2016 to serve a two-year term. The Board consists of the following members:

Chair:

Jay A. Perman, M.D., President - University of Maryland, Baltimore

Vice Chair:

Douglas Jon Liu, Senior Vice President, Head of Global Operations – Qiagen

Sciences Inc.

Appointed Members: Christopher P. Austin, M.D., Director, National Center for Advancing

Translational Sciences - U.S. National Institutes of Health

Richard A. Bendis. President and CEO - BioHealth Innovation, Inc.

Jarrod Borkat, Vice President, Corporate Strategy, Emergent BioSolutions

William Hearl, President and CEO - Immunomic Therapeutics, Inc.

Laurie Locascio, Vice President of Research, University of Maryland, College Park

Theodore J. Olsen, President and CEO - PathSensors, Inc.

Wendy Perrow, MBA, CEO - AsclepiX Therapeutics

Karen L. Proudford, Ph.D., Associate Professor of Management and Director,

Graves Honor Program - Earl G. Graves School of Business & Management Morgan State University; President, William E. Proudford Sickle Cell Fund, Inc.

Sanjay K. Rai, Ph.D., Chief Academic Officer and Senior Vice President for

Academic Affairs - Montgomery College

David W. Smith, Ph.D., Vice President, Global Business Development, Emerging

Technologies - Lonza Walkersville, Inc.

Col. Andrea Stahl, Ph.D., Director, MRMC CBRN Defense Medical Research Coordinating Office and JPC-Radiation Health Effects - U.S. Army Medical

Research & Material Command

Frank F. Weichold, M.D., Ph.D., Director, Critical Path and Regulatory Science Initiatives, Office of the Commissioner – U.S. Food and Drug Administration Christy Wyskiel, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures, Johns Hopkins University

Standing Member:

R. Michael Gill, Secretary – Maryland Department of Commerce George Davis, Chief Executive Officer - TEDCO

Summary of Activities

First Meeting

Chairman Perman convened the fiscal year's first meeting of the LSAB on October 23, 2017 at the University of Maryland BioPark, 801 West Baltimore Street, Baltimore MD. The meeting included a presentation and update on the University of Maryland, BioPark in West Baltimore. Jim Hughes, Chief Enterprise and Economic Development Officer and Vice President for UMB spoke about efforts and initiatives of the UMB BioPark and its dedication to research, commercialization and entrepreneurship. Additional discussions during the first meeting focused on new initiatives of the LSAB that are underway, the vision of EXCEL Maryland, and to agree on the recommendations for accelerating the growth of the BioHealth industry in Maryland.

Dr. Perman, LSAB Chair, spoke about the vision for the LSAB in 2017-2018. He discussed the need to align LSAB efforts to those of the EXCEL Maryland initiative and the need to create operational and effective synergies. An update was given on the findings of the EXCEL Maryland initiative. Phase I which is now complete, described the five critical areas for improving Maryland's innovation environment. Phase II, currently ongoing, will continue to create a roadmap for focusing the state's efforts to establish preeminence in the cyber and life sciences arenas. Among other initiatives, is the concept of the development of an Innovation Hub to be tasked with the implementation of coordination of the EXCEL initiatives.

Additional discussion ensued regarding progress toward implementing the LSAB recommendations since the April 2017 LSAB meeting. Bret Schreiber, Senior Director, Office of BioHealth and Life Sciences, Maryland Department of Commerce, discussed the progress to date in the following recommendations: Leverage and grow the current ASSET base, Increase CONNECTIVITY among and awareness of Maryland's BioHealth assets and resources, Increase availability and access to CAPITAL for advanced stage BioHealth companies and Grow TALENT pool of experienced BioHealth entrepreneurs, business leaders, graduates and scientists with commercially relevant experience.

Additional conversation followed regarding federal commercialization opportunities. Last year the LSAB implemented a Task Force on Federal Commercialization initiatives. The Task Force addressed federal legislation related to the extension of an SBIR PILOT program. The Task Force will continue its work in 2018 focusing on "conflict of interest" policy in an attempt to increase commercial opportunities in the State's federal labs.

Prior to this meeting, Dr. Perman had requested that the Commerce Team prioritize additional recommendations for focus going forward into 2018. Bret Schreiber presented the following initiatives, which were approved by the LSAB Committee as top priorities for FY 2018

• Implementing New Proposals

- Assets Incentivize developers and companies to expand manufacturing facilities;
- Capital Ensure existing Maryland BioHealth funding programs are capitalized;
- Capital Establish a public-private competition to increase scalable risk capital; and
- Talent Create incentive program to attract, retain, and support C-Level entrepreneurs.

Second Meeting

The second LSAB meeting was a conference call held on December 19, 2017. An update was given regarding a recent announcement by Governor Hogan on new STEM Industries, cell therapy manufacturing, and economic development initiatives through the EXCEL Maryland initiative. A vision statement for the EXCEL initiative was discussed. Governor Hogan and his administration will launch a \$33 million partnership with the University System of Maryland to increase degrees awarded in STEM-related fields. In addition, two workforce initiatives will be further developed and funded to enhance internships in the state of Maryland. The Maryland Technology Internship Program, and a technology internship platform, called In-MD, which will allow for more students to become involved in STEM-related fields. A multimillion-dollar investment to establish a Center for Cell Therapy Manufacturing in conjunction with Johns Hopkins will be launched, and will give Maryland the opportunity to become the lead state in regenerative medicine.

Commerce also updated the LSAB on the More Jobs for Marylanders Act 2.0, which will expand jurisdictions in the State to include Garrett, Caroline, Kent and Wicomico Counties. These counties will be able to choose three industries where they can develop NAICS codes, which will aid in expanding job creation and tax credits.

The LSAB also decided to organize five working groups to help expedite and initiative the work of the LSAB. Bret Schreiber from Commerce introduced the Chairs and focus areas of the LSAB Working Groups for 2018:

- Working Group 1 (Leverage and grow current ASSET base and accelerate commercialization): Bob Storey, Chair
- Working Group 2 (Increase Connectivity among and awareness of Maryland's BioHealth assets and resources): Doug Liu, Chair
- Working Group 3 (Increase availability and access to CAPITAL for early through advanced state BioHealth companies): Wendy Perrow, Chair
- Working Group 4 (Grow Talent Pool of experienced BioHealth entrepreneur's, business leaders, graduates and scientists with commercially relevant experience): Laurie Locascio, Chair
- Working Group 5 (Federal Task Force on Commercialization) Rich Bendis, Chair

Commerce Deputy Secretary Ben Wu spoke about the federal commercialization opportunities and preparations for a Technology Transfer Summit, which will be held in the second quarter. Updates were also given on the establishment of the Fischell Institute for BioMedical Devices, which is a UM Ventures project and will be a great resource for the medical device community. The Fischell Institute will be a resource and can help medical device companies with training, FDA authorization, and help in pursuing commercialization opportunities. Dr. Perman, LSAB Chair, announced the ribbon cutting at the University of Maryland and GRID, the Graduate Resource Innovation District where students can come to work together in hopes to become innovators and entrepreneurs. The LSAB also discussed a partnership with the FDA and payer industry regarding the establishment of an approval process for medical technologies. The FDA wants to take on the approval role. NIH is also interested in supporting this initiative by providing financial support. Bret Schreiber mentioned attraction and expansion opportunities for companies wanting to grow and/or locate in the State, specifically 7 expansion opportunities which will create 1,400 jobs.

Third Meeting

The third meeting of the LSAB in FY 2018 was held on May 15, 2018 at the Maryland Department of Commerce, World Trade Center, 401 East Pratt Street, Baltimore, MD. The Maryland Department of Commerce provided an update on the 2018 Maryland Technology Transfer Summit, which was organized in conjunction with NIST. The main purpose was to seek opportunities to enhance Technology Transfer from our Federal and University Labs while also seeking to enhance awareness of commercialization opportunities and the tremendous momentum already occurring at our Federal and University Labs. Nearly 300 individuals attended the Summit from across the country. The Summit lead to the formation of the Maryland Commercialization Council, whose priorities are the development of a foundational document to highlight a path toward enhanced commercialization success for Maryland's Federal and University Labs, the development of an asset map to highlight Maryland's key life science capabilities, and implementation of NIST's Return on Investment Initiative. The Council is also working with NIST to organize a series of events highlighting transformational innovations and technologies to include such areas as gene therapy, personalized medicine, and medical devices. The events are sponsored by the U.S. Department of Commerce, Maryland Department of Commerce, the Federal Lab Consortium, and the Maryland Life Sciences Advisory Board. The events will seek to help to identify assets, resources, and market differentiators and promote them within and outside Maryland to increase connection and collaboration opportunities throughout the state and beyond.

Commerce also provided on update on actions of the five LSAB working groups, which collectively, met fifteen times. Progress of the LSAB working groups will be reported later in the report. The Office of BioHealth and Life Sciences (BHLS) on behalf of the LSAB was also busy in preparation for the Bio 2018 International Convention in Boston to take place the first week of June 2018. BHLS led successful efforts to continue its primary goal of seeking to successfully help with the expansion, recruitment and retention of companies in the life sciences sector with a direct goal of creating jobs, economic growth, opportunity and vitality. To that end, following are the top growth accomplishments in FY 2018:

> Paragon BioServices: 200 New Jobs

➤ Supernus Pharmaceuticals: 160 New/156 Retained Jobs

➤ GSK Rockville Biomanufacturing: 120 New Jobs

➤ Viela Bio: 100 New Jobs

MacroGenics: 98 New Jobs

➤ Intralytix: 30 New Jobs

Following Bret Schreiber's updates, Phil Singerman, NIST, Associate Director for Innovation and Industry Services, provided an update on the "Unleashing American Innovation," initiative, the purpose of which is to advance the President's Management Agenda to modernize government for the 21st century and its Lab-to-Market CAP Goal. NIST has launched an ambitious initiative in coordination with the White House Office of Science and Technology Policy to enable greater return on investment (ROI) from the Federal government's \$150 billion annual R&D investment in its federal labs. The Lab-to-Market is a cross-agency priority (CAP) goal of the recently released President's Management Agenda to modernize government for the 21st century to significantly improve Transfer of Federally-Funded Technologies from Lab-to-Market.

The Lab-to-Market CAP Goal is co-led by the Department of Commerce via NIST and the White House Office of Science & Technology Policy (OSTP). NIST, in coordination with White House's OSTP, will advance the President's Management Agenda and its Lab-to-Market CAP Goal through the ROI Initiative. The National Science and Technology Council Lab-to-Market Subcommittee will coordinate, review, and implement interagency priorities for this CAP Goal. The goal is to maximize the transfer of federal investments in science and technology into value for America; to meet current and future economic and national security needs in a rapidly shifting technology marketplace and enhance U.S. competitiveness globally. Additionally, NIST will seek to attract greater private sector investment to create innovative products, processes, services, as well as new businesses and industries.

NIST will help to assess, streamline, and accelerate the transfer of technology from Lab-to-Market; specifically to;

- Identify critically needed improvements to Federal technology transfer policies, practices, and efforts;
- Seek broad input from Federal R&D, intellectual property and technology transfer stakeholders;
- Identify Core technology transfer principles and practices that should be protected, and those which should be adapted or changed, and;
- Identify approaches to improve efficiency and reduce regulatory burdens for technology transfer to attract private sector investment in later-stage R&D, commercialization, and advanced manufacturing.

NIST will also explore new partnering models and technology transfer mechanisms with the private sector, academia, other Federal agencies, state, and other public-sector entities to support technology development and maturation. NIST will seek new approaches to reduce/eliminate barriers and enable accelerated commercialization in areas of strategic national importance. They will identify better metrics and methods to evaluate ROI outcomes and impacts from Federal R&D investment. They will seek new approaches to motivate significantly increased technology transfer outcomes from the Federal sector, universities, and research organizations.

NIST will also be seeking a national request for information (RFI). The RFI will identify the following questions;

- What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?
- What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?
- What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?
- What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy?

LSAB Working Group Meetings

In addition to the full LSAB meetings, the five Working Groups of the LSAB met several times in FY 2018. Following are top activities for the Working Groups:

Working Group 1: Leverage and grow current Asset base and accelerate commercialization

Chair - Bob Storey, Principal, MVRCO

Mission/Goals: The mission of Working Group 1 is to establish the Maryland Medical Device GPS (Guidance, Prioritization, Support), a roadmap initiative to drive medical device innovations through the marketplace to patients and the healthcare system by de-risking investments. This will be driven by incorporating the priority needs of payers, providers and patients. The GPS effort utilizes Maryland's concentrated clinical and government resources (scientific, regulatory and coverage/reimbursement) as a guide to market validation. This initiative provides information and analysis on current high-priority areas in disease management and public health to incentivize investment and accelerate the pipeline of novel ideas to patient care.

The Maryland Medical Device Test Bed will accelerate innovation by de-risking investment in medical devices. This will be done first by identifying high-priority, unmet health needs among a wide range of stakeholders, and second by establishing qualitative and quantitative performance criteria. This is in order so entrepreneurs can innovate around these needs with a higher degree of confidence that the device will comply with the clearance/approval processes by FDA, covered/reimbursed by CMS and other payers, and adopted by the healthcare community

Activity

Regular meetings of the Governing Committee:

Seven meetings: (January 4th; February 9th; February 27th; March 22nd; April 19th; May 29th; June 28th).

One meeting of the High Priority Health Needs sub-committee: (June 29th). Groups represented include FDA, CMS, MDH, MHA and CareFirst.

Working Group 2: Increase Connectivity Among and Awareness of Maryland's BioHealth Assets and Resources

Chair - Doug Liu, Senior Vice President for Global Operations, Qiagen

Mission/Goals: The Life Science Advisory Board identified the limitations posed by the geographic distribution of the state's BioHealth assets. This issue underscored the need for a dedicated working group aimed to coalesce the industry's stakeholders including not-for profit institutions, academic and federal laboratories, as well as biotechnological, pharmaceutical, medical device and health tech companies. This working group held two full meetings, among several smaller ones in FY 2018, to undertake these initiatives:

- Devise a marketing strategy that would increase brand awareness of Maryland's BioHealth cluster and to align our message with the BioHealth Capital Region branding;
- Create an interactive asset map of the State's companies and research institutions;
- Create an online platform called the "Maryland Innovation Marketplace" used to facilitate synergistic opportunities between startups and mature companies; and

• Establish a cell manufacturing Center of Excellence in the state.

Working Group 3: Increase Availability and Access to Capital for Early through Advanced Stage BioHealth Companies

Chair - Wendy Perrow, CEO, AsclepiX

Mission/Goals: Although there are funding opportunities for startup companies through the Biotechnology Investment Incentive Tax Credit and TEDCO's programs, including the Maryland Innovation Initiative and Maryland Venture Fund, the Life Science Advisory Board identified that the demand for startup funding remained unmet. As a result, this dedicated working group aimed to garner investment for early-stage companies. They held two full meetings in FY 2018 and the initiatives undertaken by this working group included:

- Develop the UMB Maryland Asset Delivery Model as an institution dedicated to accelerating and funneling innovative technologies from federal and university labs to the market;
- Attract C-level talent and train local, aspiring leadership team;
- Attract venture capital investment through fund-matching and commit private funds to invest local companies;
- Create a state-funded Life Sciences MD Venture Capital Investment Fund for scalable risk capital for early stage life sciences companies through a public-private partnership; and
- Establish a network of high-net worth, experienced life science entrepreneurs to become investors in Maryland life

Working Group 4: Grow Talent pool of experienced BioHealth entrepreneurs, business leaders, graduates and scientists with commercially relevant experience

Chair - Laurie Locasio, Vice President for Research, University of Maryland

Mission/Goals: The working group is focusing on building the biohealth and talent pipeline by exploring badging and credentialing initiatives that may assist the life science industry identify talent from Maryland's high school graduates, as well as Two-year degree and Four-year degree holders. The Working Group is also analyzing the gaps that exist in developing C-level talent within the state, to lead smaller, high-growth companies. Working group 4 met twice in FY 2018. This working group is also helping to coordinate the Bridges to BioTech Fellows Program. The Bridges to Biotech program connects the pipeline to the employer. The program's goals are to help trainees with advanced degrees access the wide range of careers open to them. They want to better understand the industrial environment, and the skills needed for success as they start their job search to launch their career following graduation. Four employers hosted Bridges to Biotech sessions in FY 2018 – BioReliance; Personal Genome Diagnostics; Noble Life Sciences; Emergent BioSolutions. More than 100 trainees (Ph.D./Post-doc level) participated in these sessions.

Working Group 5: Task Force on Federal Commercialization

Chair - Rich Bendis, President and CEO, BioHealth Innovation

Mission/Goals: Maryland universities and federal labs have traditionally excelled in basic research, but historically, haven't succeeded in driving innovation from the laboratory to the marketplace. The products generated at university and federal labs are typically underdeveloped, therefore this taskforce was created to

identify and address the barriers to technology transfer, in addition to supporting scientist entrepreneurs wishing to commercialize their discoveries. The two full meetings in FY 2018 aimed to address the following initiatives:

- Organize a Technology Transfer Summit co-sponsored by the National Institute of Standards and Technology and the Maryland Department of Commerce;
- Write a white paper aimed to help policy-makers address the implementation of Conflict of Interest regulations in Federal labs;
- Write an opinion editorial to emphasize the need and to showcase the recommendations for technology transfer; and
- Secure SBIR Reauthorization by way of collaborating with the Small Business Administration.

Appendix 1 - LSAB Meeting Minutes - October 23, 2017

MINUTES

MEETING DATE: October 23, 2017

TIME: 9:30AM – 12:00PM

LOCATION: University of Maryland BioPark

801 W Baltimore Street Baltimore, MD 21201

Welcome

Attendees were welcomed by Jay Perman, Chairman of Maryland Life Sciences Advisory Board (LSAB) and the President of the University of Maryland, Baltimore (UMB). Prior to this meeting, Dan Abdun-Nabi led the LSAB meetings as Chairman. Dr. Perman thanked his predecessor for his leadership and dedication of his time and talents to lead the LSAB.

Call to Order

Chair Perman introduced himself and asked everyone to as well. Following Secretary Gill's comments on behalf of the Governor, all LSAB members introduced themselves. Jim Hughes spoke about efforts and initiatives of the UMB BioPark and its dedication to research, commercialization and entrepreneurship. Dr. Perman convened the meeting and stated the purpose was to discuss the new initiatives that are underway, the vision of EXCEL Maryland, and to agree on the recommendations for Accelerating the Growth of the BioHealth Industry in Maryland. The Chairman reconfirmed the LSAB's desire to develop not only recommendations, but also strategies for implementation. He included the phases that have been completed and the current timeline structure. Dr. Perman graciously thanked everyone for their feedback and input.

Dr. Perman spoke about the vision for LSAB in 2017-2018. He discussed the need to align LSAB efforts to those of the EXCEL Maryland initiative and the need to create operational and effective synergies. Secretary Gill communicated a message from Governor Hogan with the members on how best to utilize resources that currently exist, while seeking to sustain national preemince and leadership in the life science arena. Dr. Perman asked for a review and acceptance of the April 10 meeting minutes. Ted Olsen moved to accept. After a second by Wendy Perrow, the minutes were approved.

Bret Schreiber presented the findings of the EXCEL Maryland initiative. Phase I which is now complete, described the five critical areas for improving Maryland's innovation environment. Phase II, currently ongoing, will continue to create a roadmap for focusing the state's efforts to establish preeminence in the cyber and life sciences arenas. Among other initiatives, is the concept of the development of an Innovation Hub to be tasked with the implementation of coordination of the EXCEL initiatives.

In the discussion that followed, George Davis, Christy Wyskiel, Mike Gill and Ben Wu, all members of the EXCEL Steering Committee, added additional insight and answered questions specifically regarding the EXCEL initiative and its relationship to the LSAB recommendations.

After a break, Dr. Perman asked Bret Schreiber to present progress toward implementing the LSAB recommendations since the April 2017 LSAB meeting. Mr. Schreiber covered the progress to date in the

following recommendations: Leverage and grow the current ASSET base, Increase CONNECTIVITY among and awareness of Maryland's BioHealth assets and resources, Increase availability and access to CAPITAL for advanced stage BioHealth companies and Grow TALENT pool of experienced BioHealth entrepreneurs, business leaders, graduates and scientists with commercially relevant experience.

Additional conversation followed regarding federal commercialization opportunities. Last year the LSAB implemented a Task Force on Federal Commercialization initiatives. The Task Force addressed federal legislation related to the extension of an SBIR PILOT program. The Task Force will continue its work in 2018 focusing on "conflict of interest" policy in an attempt to increase commercial opportunities in our federal labs.

Prior to this meeting, Dr. Perman had requested that the Commerce Team prioritize additional recommendations for focus going forward into 2018. Bret Schreiber presented the following initiatives:

- Implementing New Proposals
 - Assets Incentivize developers and companies to expand manufacturing facilities;
 - Capital Ensure existing MD BioHealth funding programs are capitalized;
 - Capital Establish a public-private competition to increase scalable risk capital; and
 - Talent Create incentive program to attract, retain, and support C-Level entrepreneurs.

Next Steps

The next meeting will take place December 19, 2017. A document detailing the discussions from this meeting will be distributed. Working groups will be established and a chairman of each group will be asked to lead this position.

Adjourn

Chair Perman and Secretary Mike Gill thanked everyone for their participation and adjourned the meeting.

Board Members in Attendance

Chair:

Jay A. Perman, M.D., President - University of Maryland, Baltimore

Members: Richard (Rich) A. Bendis, President and CEO – BioHealth Innovation Inc.

Jarrod Borkat, Head, External Collaborations, Biotech Hubs and Government Contracting-MedImmune

William (Bill) Hearl, Ph.D., CEO - Immunomic Therapeutics

Theodore (Ted) J. Olsen, President and CEO - PathSensors, Inc.

Wendy Perrow, MBA, CEO - AsclepiX Therapeutics

Karen L. Proudford, Ph.D., President, William E. Proudford Sickle Cell Fund, Inc.; Associate Professor of Management and Director, Graves Honor Program - Morgan State University

Col. Andrea Stahl, Ph.D., Director, MRMC CBRN Defense Medical Research Coordinating Office and JPC-Radiation Health Effects – USAMRMC

Frank F. Weichold, M.D., Ph.D., Director, Critical Path and Regulatory Science Initiatives, Office of the Commissioner – U.S. FDA

Christy Wyskiel, MBA, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures-- Johns Hopkins University

Ex Officio:

R. Michael Gill, Secretary - Maryland Department of Commerce

George Davis, President - TEDCO

Board Members Not in Attendance

Vice Chair: Douglas Jon Liu, Senior Vice President, Head of Global Operations – Qiagen Sciences Inc.

Members: Christopher P. Austin, M.D., Director, NCATS, U.S. National Institutes of Health

Laurie Locascio, Vice President, Research - UMCP

Sanjay K. Rai, Ph.D., Senior Vice President for Academic Affairs – Montgomery College

David W. Smith, Ph.D., Vice President, Global Business Development, Emerging Technologies – Lonza Walkersville, Inc.

Bob Storey, Principal, MVR Company

Speakers and Guests in Attendance

Benjamin H. Wu, Deputy Secretary/Chief Operating Officer, Maryland Department of Commerce

Steve Pennington, Managing Director, Business and Industry Sector Development, Maryland Department of Commerce

Bret Schreiber, Senior Director, BioHealth & Life Sciences, Maryland Department of Commerce

Brad E. Fackler, Director, BioHealth & Life Sciences, Maryland Department of Commerce

Virginia Crews, Business Development Manager, BioHealth & Life Sciences, Maryland Department of Commerce

Nina Lamba, Business Development Manager, BioHealth & Life Sciences, Maryland Department of Commerce

Chelsie Caizzi, Business Development Associate, BioHealth & Life Sciences, Maryland Department of Commerce

Dean Storm, Digital Content Manager, Marketing & Communications, Maryland Department of Commerce

Julie Woepke, Director, Maryland Economic Development Commission, Maryland Department of Commerce

Tom Sadowski, Vice Chancellor for Economic Development, University System of Maryland

Jim Hughes, Vice President at University of Maryland, Baltimore

Judy Costello, Managing Director, Economic Development, BioHealth Innovation

Jen LaHatte, Business Policy Analyst, Maryland Department of Commerce

Appendix 2 - LSAB Meeting Minutes - December 19, 2017

MINUTES

MEETING DATE: December 19, 2017

TIME: 9:30AM – 11:00AM

LOCATION: Conference Call

Welcome

Attendees were welcomed by Jay Perman, Chairman of Maryland Life Sciences Advisory Board (LSAB) and the President of the University of Maryland, Baltimore (UMB) via the Conference Call.

Call to Order

Dr. Perman introduced himself and asked everyone to do so as well when they joined the call. Secretary Mike Gill commented on a recent Governor's Press Release on December 13th, 2017. This was in regards to the announcement of new STEM Industries, cell therapy manufacturing, and economic development initiatives. Dr. Perman asked for approval and acceptance of the October 23rd LSAB Minutes. He also recommended that the discussion of the Federal Commercialization Opportunities be included in the Minutes as well. Rich Bendis moved to accept the minutes and after the second by Jarrod Borkat, the minutes were approved.

Bret Schreiber was asked by Dr. Perman to speak about the updates for EXCEL Maryland. Recently there was an EXCEL Steering Committee Meeting and during this discussion, the vision statement for EXCEL was finalized. Governor Hogan and his administration will launch a \$33 million partnership with the University System of Maryland to increase degrees awarded in STEM-related fields. In addition, two workforce initiatives will be further developed and funded to enhance internships in the state of Maryland. The Maryland Technology Internship Program, and a technology internship platform, called IN-MD, which will allow for more students to become involved in STEM-related fields. A multimillion-dollar investment to establish a Center for Cell Therapy Manufacturing in conjunction with Johns Hopkins will be launched, and will give Maryland the opportunity to become the lead state in regenerative medicine.

Steve Pennington announced the More Jobs for Marylanders Act 2.0, which will expand the bill to include Garrett, Caroline, Kent and Wicomico Counties. These counties will be able to choose three industries where they can develop NAICS codes, which will aid in expanding job creation and tax credits.

Bret Schreiber introduced the chairman of each LSAB Working Group for this year and asked for board members or a designee to join a group:

- Working Group 1 (Leverage and grow current ASSET base and accelerate commercialization): Bob Storey
- Working Group 2 (Increase Connectivity among and awareness of Maryland's BioHealth assets and resources): Doug Liu
- Working Group 3 (Increase availability and access to CAPITAL for early through advanced state BioHealth companies): Wendy Perrow

• Working Group 4 (Grow Talent Pool of experienced BioHealth entrepreneur's, business leaders, graduates and scientists with commercially relevant experience): Laurie Locascio

Ben Wu spoke about the Federal Commercialization Opportunities and how they are now preparing for the Tech Transfer Summit, which will be in the Second Quarter. Maryland Universities will be asked to confirm their participation and promote synergies with this task force.

Bret Schreiber announced the electronic LSAB newsletter which will broadcast updates and gives an opportunity for interaction between board members. The Fischell Institute for BioMedical Devices is a UM Ventures project and will be a great resource for the medical device community. The Center should be used as a resource and can help with academics, FDA authorization, and pursue commercialization opportunities.

Dr. Perman announced the ribbon cutting at the University of Maryland and GRID, the Graduate Resource Innovation District where students can come to work together in hopes to become innovators and entrepreneurs.

Bob Storey spoke about the FDA and payer industry approval process for medical technologies. The FDA wants to take on the approval role. NIH is also interested in supporting this initiative by providing support. Maryland can become the test bed in this process.

Bret Schreiber mentioned attraction and expansion opportunities, specifically 7 expansion opportunities which will create 1,400 jobs. The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) received a \$70 million award from NIST. The University of Maryland College Park is a colead with the University of Delaware.

Next Steps

Dr. Perman has asked the for a mid-meeting in January to discuss the progress of each Working Group initiative.

Adjourn

Dr. Perman thanked everyone for their participation in the call and adjourned the meeting.

Board Members in Attendance

Chair:

Jay A. Perman, M.D., President - University of Maryland, Baltimore

Vice Chair: Douglas Jon Liu, Senior Vice President, Head of Global Operations – Qiagen Sciences Inc.

Members:

Christopher P. Austin, M.D., Director, NCATS, U.S. National Institutes of Health

Richard (Rich) A. Bendis, President and CEO – BioHealth Innovation Inc.

Jarrod Borkat, Head, External Collaborations, Biotech Hubs and Government Contracting-MedImmune

William (Bill) Hearl, Ph.D., CEO - Immunomic Therapeutics

Laurie Locascio, Vice President, Research - UMCP

Theodore (Ted) J. Olsen, President and CEO - PathSensors, Inc.

Wendy Perrow, MBA, CEO - AsclepiX Therapeutics

Karen L. Proudford, Ph.D., President, William E. Proudford Sickle Cell Fund, Inc.; Associate Professor of Management and Director, Graves Honor Program - Morgan State University

Sanjay K. Rai, Ph.D., Senior Vice President for Academic Affairs - Montgomery College

David W. Smith, Ph.D., Vice President, Global Business Development, Emerging Technologies – Lonza Walkersville, Inc.

Col. Andrea Stahl, Ph.D., Director, MRMC CBRN Defense Medical Research Coordinating Office and JPC-Radiation Health Effects – USAMRMC

Bob Storey, Principal, MVR Company

Frank F. Weichold, M.D., Ph.D., Director, Critical Path and Regulatory Science Initiatives, Office of the Commissioner – U.S. FDA

Christy Wyskiel, MBA, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures-- Johns Hopkins University

Ex Officio:

R. Michael Gill, Secretary – Maryland Department of Commerce

George Davis, President – TEDCO

Board Members Not in Attendance

Members: Christy Wyskiel, MBA, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures-- Johns Hopkins University

Speakers and Guests in Attendance

Benjamin H. Wu, Deputy Secretary/Chief Operating Officer, Maryland Department of Commerce

Steve Pennington, Managing Director, Business and Industry Sector Development, Maryland Department of Commerce

Bret Schreiber, Senior Director, BioHealth & Life Sciences, Maryland Department of Commerce

Brad E. Fackler, Director, BioHealth & Life Sciences, Maryland Department of Commerce

Virginia Crews, Business Development Manager, BioHealth & Life Sciences, Maryland Department of Commerce

Nina Lamba, Business Development Manager, BioHealth & Life Sciences, Maryland Department of Commerce

·Chelsie Caizzi, Business Development Associate, BioHealth & Life Sciences, Maryland Department of Commerce

Julie Woepke, Director, Maryland Economic Development Commission, Maryland Department of Commerce

Appendix 3 - LSAB Meeting Minutes - May 15, 2018

MINUTES

MEETING DATE: May 15, 2018

TIME:

9:00AM - 11:00PM

LOCATION:

Maryland Department of Commerce

World Trade Center, 401 East Pratt Street

Baltimore, MD 21202

Welcome

Attendees were welcomed by Jay Perman, Chairman of Maryland Life Sciences Advisory Board (LSAB) and the President of the University of Maryland, Baltimore (UMB).

Call to Order

Chair Perman introduced himself and welcomed everyone to introduce themselves. Following Deputy Secretary Wu's comments on behalf of the Governor, all LSAB members introduced themselves. Dr. Perman asked for a review and acceptance of the December 19, 2017 meeting minutes. The meeting minutes were approved.

Progress Since December 2017 - Update and Next Steps

Bret Schreiber provided an update on the 2018 Maryland Technology Transfer Summit: The BHLS office in partnership with NIST organized a successful Maryland Technology Transfer Summit. The main purpose was to seek opportunities to enhance Technology Transfer from our Federal and University Labs while also seeking to enhance awareness of commercialization opportunities and the tremendous momentum already occurring at our Federal and University Labs. Nearly 300 individuals attended the Summit from across the country. The Summit lead to the formation of the Maryland Commercialization Council, whose priorities are the development of a foundational document to highlight a path toward enhanced commercialization success for Maryland's Federal and University Labs, the development of an asset map to highlight Maryland's key life science capabilities, and implementation of NIST's Return on Investment Initiative. The Council is also working with NIST to organize a series of events highlighting transformational innovations and technologies to include such areas as gene therapy, personalized medicine, and medical devices. The events are sponsored by the U.S. Department of Commerce, MD. Department of Commerce, the Federal Lab Consortium, and the Maryland Life Sciences Advisory Board. The events will seek to help to identify assets, resources, and market differentiators and promote them within and outside Maryland to increase connection and collaboration opportunities throughout the state and beyond.

Dr. Perman asked Bret Schreiber to present progress toward implementing the LSAB recommendations since the December 2017 LSAB meeting. Year to date, the LSAB working groups, collectively, met fifteen times. Progress of the LSAB working groups will be reported later in the agenda. The Office of BioHealth and Life Sciences (BHLS) on behalf of the LSAB was also busy in preparation for the Bio 2018 International Convention in Boston

to take place the first week of June 2018. BHLS led successful efforts to continue our primary goal of seeking to successfully help with the expansion, recruitment and retention of companies in the life sciences sector with a direct goal of creating jobs, economic growth, opportunity and vitality. To that end, following are the top growth accomplishments in FY 2018:

➤ Paragon BioServices: 200 New Jobs

➤ Supernus Pharmaceuticals: 160 New/156 Retained Jobs

➤ GSK Rockville Biomanufacturing: 120 New Jobs

➤ Viela Bio: 100 New Jobs

➤ MacroGenics: 98 New Jobs

> Intralytix: 30 New Jobs

NIST Presentation - "Unleashing American Innovation"

Following Bret Schreiber's updates, Phil Singerman, NIST, Associate Director for Innovation and Industry Services provided an update on the "Unleashing American Innovation," initiative, the purpose of which is to advance the President's Management Agenda to modernize government for the 21st century and its Lab-to-Market CAP Goal. NIST has launched an ambitious initiative in coordination with the White House Office of Science and Technology Policy to enable greater "Return on Investment" (ROI) from the Federal government's \$150 billion annual R&D investment in its federal labs. The Lab-to-Market is a cross-agency priority (CAP) goal of the recently released President's Management Agenda to modernize government for the 21st century to significantly improve Transfer of Federally-Funded Technologies from Lab-to-Market.

The Lab-to-Market CAP Goal is co-led by the Department of Commerce via NIST and the White House Office of Science & Technology Policy (OSTP). NIST, in coordination with White House's OSTP, will advance the President's Management Agenda and its Lab-to-Market CAP Goal through the ROI Initiative. The National Science and Technology Council Lab-to-Market Subcommittee will coordinate, review, and implement interagency priorities for this CAP Goal. The goal is to maximize the transfer of federal investments in science and technology into value for America; to meet current and future economic and national security needs in a rapidly shifting technology marketplace and enhance U.S. competitiveness globally. Additionally, NIST will seek to attract greater private sector investment to create innovative products, processes, services, as well as new businesses and industries.

NIST will help to assess, streamline, and accelerate the transfer of technology from Lab-to-Market; specifically to;

- Identify critically needed improvements to Federal technology transfer policies, practices, and efforts;
- Seek broad input from Federal R&D, intellectual property and technology transfer stakeholders;
- Identify Core technology transfer principles and practices that should be protected, and those which should be adapted or changed, and;

• Identify approaches to improve efficiency and reduce regulatory burdens for technology transfer to attract private sector investment in later-stage R&D, commercialization, and advanced manufacturing.

NIST will explore new partnering models and technology transfer mechanisms with the private sector, academia, other Federal agencies, state, and other public-sector entities to support technology development and maturation. NIST will seek new approaches to reduce/eliminate barriers and enable accelerated commercialization in areas of strategic national importance. They will identify better metrics and methods to evaluate ROI outcomes and impacts from Federal R&D investment. They will seek new approaches to motivate significantly increased technology transfer outcomes from the Federal sector, universities, and research organizations.

NIST will also be seeking a national "Request for Information. (RFI). The RFI will identify the following questions;

- What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?
- What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?
- What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D?
- What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy?

Four public meetings have been announced to gather additional stakeholder inputs:

- May 17, 2018, Silicon Valley USPTO Regional Office, San Jose, CA.
- May 21, 2018, Renaissance Denver Downtown City Center Hotel, Denver, CO.
- May 31, 2018, Hilton Chicago/Oak Lawn, Oak Lawn, IL.
- June 14, 2018 (simultaneous webcast), NIST Campus, Gaithersburg, MD.

LSAB Working Group Updates

Chairs of the LSAB Working Groups provided updates on their respective subcommittees. Following are the workgroups and key initiatives underway:

- Working Group 1: Leverage and Grow Current Asset Base and Accelerate Commercialization Bob Storey Chair
 - o Maryland Test Bed
- Working Group 2: Increase Connectivity Among and Awareness of Maryland's BioHealth Assets and Resources Doug Liu, Chair
 - o Maryland Asset Map and Maryland Innovation Marketplace
 - o Cell Manufacturing Hub in Frederick, Maryland
 - o NIIMBL Initiative
 - BioFab USA
- Working Group 3: Increase Availability and Access to Capital for Early through Advanced Stage BioHealth Companies Wendy Perrow Chair
 - Maryland Asset Delivery Model
 - o Fund C-level / CEO entrepreneurial talent and management attraction to Maryland
 - o Establish a public-private competition to increase scalable risk capital
 - O Seek Public / Private funding for new assets in MD
- Working Group 4: Grow Talent Pool of Experienced BioHealth Entrepreneurs, Business Leaders, Graduates and Scientists with Commercially Relevant Experience -

Laurie Locasio - Chair

- O Create a program(s) to support C-Level entrepreneurs that are proficient in both Science & Technology, and Business
- o NIIMBL Workforce Development Proposal
- o Enhancing Entry-Level Pipelines from Teaching and Training Institutions to Industry
- o Maryland Asset Delivery Model
- Federal Task Force on Commercialization Rich Bendis Chair
 - o Conflict of Interest White Paper
 - o Maryland Technology Transfer Summit Policy Deliverable
 - o Reauthorization of SBIR/STTR Funding

Next Steps

After the Bio 2018 International Convention in June, Bret Schreiber stated that the work of the subcommittees will begin again. Up to now, the goal of the subcommittees was to form membership teams. The teams then met to decide key objectives and priorities. In the summer and early fall of 2018, the goal of the subcommittees will be to determine actionable objectives and goals and most importantly, how best to accomplish the goals. The plan is to determine what is achievable versus not achievable and determine a path forward. The goal is to identify actionable items that tie back to the April 2017 final report.

Adjourn

Chair Perman and Deputy Secretary Ben Wu thanked everyone for their participation and adjourned the meeting.

Board Members in Attendance

Chair:

Jay A. Perman, M.D., President - University of Maryland, Baltimore

Members: Richard (Rich) A. Bendis, President and CEO – BioHealth Innovation Inc.

Jarrod Borkat, Head, External Collaborations, Biotech Hubs and Government Contracting—MedImmune

William (Bill) Hearl, Ph.D., CEO - Immunomic Therapeutics

Theodore (Ted) J. Olsen, President and CEO – PathSensors, Inc.

Wendy Perrow, MBA, CEO – AsclepiX Therapeutics

Karen L. Proudford, Ph.D., President, William E. Proudford Sickle Cell Fund, Inc.; Associate Professor of Management and Director, Graves Honor Program - Morgan State University

Col. Andrea Stahl, Ph.D., Director, MRMC CBRN Defense Medical Research Coordinating Office and JPC-Radiation Health Effects – USAMRMC

Frank F. Weichold, M.D., Ph.D., Director, Critical Path and Regulatory Science Initiatives, Office of the Commissioner – U.S. FDA

Christy Wyskiel, MBA, Senior Advisor to the President and Head of Johns Hopkins Technology Ventures-- Johns Hopkins University

Ex Officio:

George Davis, President – TEDCO

Board Members Not in Attendance

Ex Officio:

R. Michael Gill, Secretary – Maryland Department of Commerce

Vice Chair: Douglas Jon Liu, Senior Vice President, Head of Global Operations – Qiagen Sciences Inc.

Members: Christopher P. Austin, M.D., Director, NCATS, U.S. National Institutes of Health

Sanjay K. Rai, Ph.D., Senior Vice President for Academic Affairs – Montgomery College

David W. Smith, Ph.D., Vice President, Global Business Development, Emerging Technologies – Lonza Walkersville, Inc.

Bob Storey, Principal, MVR Company

Speakers and Guests in Attendance

Benjamin H. Wu, Deputy Secretary/Chief Operating Officer, Maryland Department of Commerce

Steve Pennington, Managing Director, Business and Industry Sector Development, Maryland Department of Commerce

Bret Schreiber, Senior Director, BioHealth & Life Sciences, Maryland Department of Commerce

Brad E. Fackler, Director, BioHealth & Life Sciences, Maryland Department of Commerce

Jon Kucskar, University of Maryland, Baltimore

Sarah Woods, Bridges

Phillip Singerman, NIST